

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ashley J. Birkett) PATENT
Serial No.: 09/930,915) Attorney Docket
Filed: August 15, 2001) ICC-102.2
For: Immunogenic HBc Chimer) 4564-81175
Particles Having Enhanced) Group Art Unit:
Stability) 1614
Examiner:)

INFORMATION DISCLOSURE STATEMENT

BOX IDS
Commissioner For Patents
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.97, Documents A1-A71 are listed on the attached Form PTO-1449. Documents A1-A5 and A15-A31 were disclosed and discussed in the text of the subject patent application. Document A13 is the published PCT application corresponding to the present application.

Document A14 is the published PCT application of a related invention by the present inventor, Application Serial No. 09/931,325 filed August 15, 2001, and Documents A6-A8 and A32-65 were disclosed and discussed in that related pending application by the inventor. Document A6, an issued U.S. patent, and Document A11, its published PCT counterpart,

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describe an invention of the present inventor that relates to a hepatitis B core-based vaccine. Documents A9, A12, A66-67 and A71 were located subsequent to the filing of this application, and thought to possibly be material because of their subject matter, and are therefore provided herewith. Document A68 is a poster presented by the inventor and co-workers in October of 1999 of results using vaccine candidates.

None of these cited documents disclose, enable or teach claimed subject matter of the present invention.

No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material disclosed is equivalent to the subject invention.

The cited documents disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the documents and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention

field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that the art or document disclosure is otherwise necessarily prior art as defined by the patent law with respect to the instant invention and application.

Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the art and documents recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application.

The recitation herein of the art and documents is not to be construed as an assertion that more pertinent art could not possibly be in existence.

If any fees or petition are believed to be necessary, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

Respectfully submitted,

By 
Irene M. Reiningger, Reg No. 48,439

December 10, 2002

Serial No. 09/930,915

- 4 -

Enclosures:

Form PTO-1449

Documents A1-A71 in 3 Binders

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Chicago, Illinois 60606

312/655-1500

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|--|-----|---|-----------|---|-------|--------------------------|-------------------------------|
| (Rev. 5/92) Comparable to Form PTO-1449 INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) | | U.S. Department of Commerce Patent and Trademark Office | | Atty. Docket No. ICC-102.1 (4564-81175) | | Serial No. 09/931,315 | |
| | | Applicants Ashley J. Birkett | | | | | |
| | | Filing Date August 15, 2001 | | | | Group | |
| U.S. PATENT DOCUMENTS | | | | | | | |
| *Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
| | A1 | 4,818,527 | 04/1989 | Thornton, et al. | 424 | 88 | |
| | A2 | 4,882,145 | 11/1989 | Thornton, et al. | 424 | 88 | |
| | A3 | 5,143,726 | 09/1992 | Thornton, et al. | 424 | 88 | |
| | A4 | 5,928,902 | 07/1999 | DeWilde, et al. | 435 | 69.3 | |
| | A5 | 5,990,085 | 11/1999 | Ireland, et al. | | | |
| | A6 | 6,231,864 | 5/2001 | Birkett | 424 | 189.1 | |
| | A7 | 5,614,194 | 3/1997 | Colman, et al. | 424 | 191.1 | |
| | A8 | 4,886,782 | 12/1989 | Good, et al. | 514 | 12 | |
| FOREIGN PATENT DOCUMENTS | | | | | | | |
| | | Document Number | Date | Country | Class | Subclass | Translation |
| | | | | | | | Yes No |
| | A9 | WO 01/98333 | 12/27/01 | PCT | | | |
| | A10 | WO 99/40934 | 8/19/99 | PCT | | | |
| | A11 | WO 00/32625 | 6/8/2000 | PCT | | | |
| | A12 | WO 01/27281 | 4/19/2001 | PCT | | | |
| | A13 | WO 02/14478 | 2/21/2002 | PCT | | | |
| | A14 | WO 02/13765 | 2/21/2002 | PCT | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | | |
| | A15 | Schodel et al., <i>J. Exp. Med.</i> (1994) 180 (3): p. 1037-46 | | | | | |
| | A16 | Pumpens et al., <i>Intervirology</i> (1995) 38 :63-74 | | | | | |
| | A17 | Metzger et al., <i>J. Gen. Virol.</i> (1998) 79 :587-590 | | | | | |
| | A18 | Hoffman et al., <i>Nat. Med.</i> (1997) 3 (1):80-83 | | | | | |
| | A19 | Conway et al., <i>Nature</i> , (1997) 386 :91-94 | | | | | |
| | A20 | Bottcher et al., <i>Nature</i> , (1997) 386 :88-91 | | | | | |
| | A21 | Zheng et al., <i>J. Biol. Chem.</i> , (1992) 267 (13):9422-9429 | | | | | |
| | A22 | Birnbaum et al., <i>J. Virol.</i> (1990) 64 , 3319-3330 | | | | | |
| | A23 | Clarke et al., <i>Vaccines</i> (1991) 91 , Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, pp.313-318 | | | | | |
| Examiner | | | | Date Considered | | | |
| *Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant. | | | | | | | |

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|--|-----|--|-----------------|---|--------------------------|
| (Rev. 5/92) Comparable to Form PTO-1449 INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) | | U.S. Department of Commerce Patent and Trademark Office | | Atty. Docket No. ICC-102.1 (4564-81175) | Serial No. 09/931,315 |
| | | Applicants Ashley J. Birkett | | | |
| | | Filing Date August 25, 2001 | | Group | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | |
| | A24 | Gallina et al. <i>J. Virol.</i> (1989) 63 :4645-4652 | | | |
| | A25 | Inada et al. <i>Virus Res.</i> , (1989) 14 :27-48 | | | |
| | A26 | Maassen et al. <i>Arch. Virol.</i> (1994) 135 :131-142 | | | |
| | A27 | Schodel et al. <i>Infect. Immunol.</i> (1994) 62 :1669-1676 | | | |
| | A28 | Ulrich et al. <i>Adv. Virus Res.</i> Vol. 50 (1998) Academic Press pages 141-182 | | | |
| | A29 | Zlotnick et al. (1997) <i>Proc. Nat'l. Acad. Sci., USA</i> , 94 :9556-9661 | | | |
| | A30 | Nierynck et al. (Oct. 1999) <i>Nature Med.</i> , 5 (10):1157-1163 | | | |
| | A31 | Kratz et al. (1999) <i>Proc. Natl. Acad. Sci., USA</i> , 96 :1915-1920 | | | |
| | A32 | Marlar, T., et al., <i>Trans. R. Soc. Trop. Med. Hyg.</i> , (1995) 89 (3): p. 307-308 | | | |
| | A33 | Garg et al., <i>Trans. R. Soc. Trop. Med. Hyg.</i> , (1995) 89 (6): p. 656-657 | | | |
| | A34 | Baird et al., <i>Am. J. Trop. Med. Hyg.</i> , (1991) 44 (5): p. 547-552 | | | |
| | A35 | Baird et al., <i>Trans R Soc Trop Med Hyg</i> , (1996) 90 (4): p. 409-411 | | | |
| | A36 | Baird et al., <i>J. Infect. Dis.</i> , (1995) 171 (6): p. 1678-1682 | | | |
| | A37 | Murphy et al., <i>Lancet</i> , (1993) 341 (8837): p. 96-100 | | | |
| | A38 | Schwartz et al., [letter]. <i>N. Engl. J. Med.</i> , (1991) 324 (13): p. 927 | | | |
| | A39 | Rieckmann et al., <i>Lancet</i> , (1989) 2 (8673): p. 1183-1184 | | | |
| | A40 | Charoenlarp et al., <i>Southeast Asian J. Trop. Med. Public Health</i> , (1973) 4 (1): p. 135-137 | | | |
| | A41 | Krotoski, [letter]. <i>N. Engl. J. Med.</i> , (1980) 303 (10): p. 587 | | | |
| | A42 | Schuurkamp et al., <i>Trans. R. Soc. Trop. Med. Hyg.</i> , (1992) 86 (2): p. 121-122 | | | |
| | A43 | Good, et al., <i>Annu. Rev. Immunol.</i> , (1998) 16 : p. 57-87 | | | |
| | A44 | Clyde et al., <i>Am. J. Med. Sci.</i> , (1973) 266 (6): p. 398-403 | | | |
| | A45 | Rieckmann et al., <i>Trans. R. Soc. Trop. Med. Hyg.</i> , (1974) 68 (3): p. 258-259 | | | |
| | A46 | Zavala et al., <i>Science</i> , (1985) 228 (4706): p. 1436-40 | | | |
| | A47 | Nussenzweig et al., <i>Ciba Found. Symp.</i> , (1986) 119 : p. 150-163 | | | |
| | A48 | Etlinger et al., <i>Immunology</i> , (1988) 64 (3): p. 551-558 | | | |
| | A49 | Etlinger et al., <i>J. Immunol.</i> , (1988) 140 (2): p. 626-633 | | | |
| | A50 | Herrington et al., <i>Nature</i> , (1987) 328 (6127): p. 257-259 | | | |
| Examiner | | | Date Considered | | |
| *Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | |

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|--|-----|---|-----------------|---|---------------------------|
| (Rev. 5/92) Comparable to Form PTO-1449 INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) | | U.S. Department of Commerce Patent and Trademark Office | | Atty. Docket No. ICC-102.1 (4564-81175) | Serial No. 09/931,3155 |
| | | Applicants Ashley J. Birkett | | | |
| | | Filing Date August 25, 2001 | | Group | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | |
| | A51 | Ballou et al., <i>Lancet</i> , (1987) 1(8545): p. 1277-1281 | | | |
| | A52 | Good et al., <i>Science</i> , (1987) 235(4792): p. 1059-62 | | | |
| | A53 | Calvo-Calle et al., <i>J. Immunol.</i> , (1993) 150(4): p. 1403-1412 | | | |
| | A54 | Moreno et al., <i>Int. Immunol.</i> , (1991) 3(10): p. 997-1003 | | | |
| | A55 | Stoute et al., <i>N. Engl. J. Med.</i> , (1997) 336(2): p. 86-91 | | | |
| | A56 | Stoute et al. <i>J. Infect Dis.</i> (1998 Oct) 178(4):1139-44 | | | |
| | A57 | Milich et al., <i>Science</i> , (1986) 234(4782): p. 1398-1401 | | | |
| | A58 | Herrington et al., <i>Am J Trop Med Hyg.</i> (1991) 45(6): p. 695-701 | | | |
| | A59 | Schodel et al., <i>Behring Inst. Mitt.</i> (1997) (98): p. 114-119 | | | |
| | A60 | Seifer et al., <i>Intervirology</i> (1995) 38:47-62 | | | |
| | A61 | Qari et al. <i>Lancet</i> (1993) 341:780-783 | | | |
| | A62 | Moreno et al. <i>J. Immunol.</i> (1993) 151(1): 489-499 | | | |
| | A63 | Hoffman et al. <i>Malaria Vaccine Development</i> , Chapter 3: Attacking the Infected Hepatocyte, 1996 American Society for Microbiology, Washington, D.C., pp. 35-75 | | | |
| | A64 | Calvo-Calle et al. <i>J. Immunol.</i> (1997) 159(3): p. 1362-1373 | | | |
| | A65 | Coatney et al. (1962) 9:290-293 | | | |
| | A66 | Krüger et al. <i>Biol. Chem.</i> (1999) 380:275-276 | | | |
| | A67 | Nardin et al. <i>J. Exp. Med.</i> (1982) 156:20-30 | | | |
| | A68 | Poster presented by J. Haron at the Center for Advanced Technology and Medicine (CABM) Symposium, Rutgers University Medical Center on October 13-14, 1999 | | | |
| | A69 | Isagulians et al. <i>Immunol. Ltr.</i> (1994) 42:173-178 | | | |
| | A70 | Schodel et al. <i>J. Biotechnol.</i> (1996) 44:91-96 | | | |
| | A71 | Wynne et al., <i>Mol. Cell</i> (June 1999) 3:771-780 | | | |
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| Examiner | | | Date Considered | | |
| *Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | | | | | |